Form Approved: OMB No. 0910 - 0297 Expiration Date: March 31, 2022. See instructions for OMB Statement, below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	PRESCRIPTION DRUG USER FEE COVERSHEET FY 2021

A completed form must be signed and accompany each new drug or biologic product application. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment instructions and fee rates can be found on FDA's website:
http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119184.htm

1. APPLICANT'S NAME AND ADDRESS	4. BLA SUBMISSION TRACKING NUMBER (STN) / NDA NUMBER
Modernatx, Inc. (b) (6) 200 Technology Sq Cambridge MA 02139-3578 US	125752
2. NAME AND TELEPHONE NUMBER OF REPRESENTATIVE (b) (6)	5. DOES THIS APPLICATION REQUIRE CLINICAL DATA FOR APPROVAL? [X] YES [ ] NO IF YOUR RESPONSE IS "NO", STOP HERE AND SIGN THIS FORM. IF RESPONSE IS "YES", CHECK THE APPROPRIATE RESPONSE BELOW: [X] THE REQUIRED CLINICAL DATA ARE CONTAINED IN THE APPLICATION [ ] THE REQUIRED CLINICAL DATA ARE SUBMITTED BY REFERENCE TO:
3. PRODUCT NAME mRNA-1273	6. USER FEE I.D. NUMBER PD3017990

7. ARE YOU REDEEMING A PRIORITY REVIEW VOUCHER FOR THE TREATMENT OF TROPICAL DISEASES? [ ] YES [X] NO

PRIORITY REVIEW VOUCHER NUMBER:

8. ARE YOU REDEEMING A PRIORITY REVIEW VOUCHER FOR MEDICAL COUNTER MEASURES? [ ] YES [X] NO

PRIORITY REVIEW VOUCHER NUMBER:

9. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(F) of the Federal Food,Drug, and Cosmetic Act
[ ] THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALLY

10. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION?
[ ] YES [X] NO
If a waiver has been granted, include a copy of the official FDA notification with your submission.

Privacy Act Notice:
This notice is provided pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. The collection of this information is authorized by 21 U.S.C. 371, 379, 379e, 379h, 379h-1, 379j, 379j-12, 379j-21, 387s, and 393(d)(2); 42 U.S.C. 263b(r)(1); 5 U.S.C. 301 and 552; and 42 U.S.C. 3101. FDA will use the information to assess, collect and process user fee payments, and, facilitate debt collection under the Debt Collection Improvement Act. FDA may disclose information to courts and the Department of Justice in the context of litigation and requests for legal advice; to other Federal agencies in response to subpoenas issued by such agencies; to HHS and FDA employees and contractors to perform user fee services; to the National Archives and Records Administration and General Services Administration for records management inspections; to the Department of Homeland Security and other Federal agencies and contractors in order to respond to system breaches; to banks in order to process payment made by credit card; to Dun and Bradstreet to validate submitter contact information, and to other entities as permitted under the Debt Collection Improvement Act. Furnishing the requested information is mandatory. Failure to supply the information could prevent FDA from processing user fee payments. Additional detail regarding FDA's use of information is available online: http://www.fda.gov/RegulatoryInformation/FOI/PrivacyAct/default.htm.

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PRINTED NAME AND SIGNATURE OF AUTHORIZED REPRESENTATIVE	TITLE	DATE
DocuSigned by: (b) (6) Signer Name: (b) (6) Signing Reason: I approve this document Signing Time: 27-May-2021 | 13:30 PDT (b) (6)	(b) (6)	

11. USER FEE PAY[illegible]OR THIS APPLICATION
$2,875,842.00

Form FDA 3397 (04/19)

INSTRUCTIONS FOR COMPLETING PRESCRIPTION DRUG USER FEE COVER SHEET FORM FDA 3397

Form FDA 3397 is to be completed for and submitted with each new drug or biologic product original application submitted to the Agency. Form FDA 3397 should be placed in the first volume of the application with the application (FORM FDA 356(h)) form. Form FDA 3397 is to be completed on-line at https://userfees.fda.gov/OA_HTML/pdufaCAcdLogin.jsp. If you need assistance in completing the form call 301-796-7200 or email: userfees@fda.gov.

NOTE: Complete this form FDA 3397 for:

* 505(b) and 351(a) Original Applications
* Resubmission of 505(b) and 351(a) Original Applications after a Refuse to File
* Resubmissions of 505(b) and 351(a) Original Applications Withdrawn before the filing date

ITEM NO.	INSTRUCTIONS
1-2.	**Self-explanatory**
3.	**PRODUCT NAME:** Include generic or proper name and trade name, as applicable.
4.	**BLA STN / NDA NUMBER:** Please include only a NDA number or a BLA STN, as applicable. **FOR AN ORIGINAL BIOLOGIC LICENSE APPLICATION (BLA):** Indicate the 6-digit BLA number (Submission Tracking Number (STN)) if pre-assigned, otherwise leave blank. **FOR DRUG PRODUCTS:** Indicate the new drug application (NDA) number. NDA numbers can be obtained by completing the information at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm114027.htm.
5.	**CLINICAL DATA:** The definition of 'clinical data' for the assessment of user fees is found in FDA's Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees. FDA's guidance on the definition of clinical data can be found on FDA's web site: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf.
6.	**USER FEE I.D. NUMBER:** Please include the ID number (generated when completing Form FDA 3397) on the application payment check.
7-8.	**PRIORITY REVIEW VOUCHER:** If you are redeeming a priority review voucher awarded to a sponsor of a tropical disease product application (see section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), please include the priority review voucher number assigned when the tropical disease or medical countermeasure product was approved. See FDA´s Guidance for Industry: Tropical Disease Priority Review Vouchers for further information. FDA´s guidance can be found on FDA´s web site: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080599.pdf. If you are redeeming a priority review voucher awarded to a sponsor of a medical countermeasures application (see section 565A of the Federal Food, Drug, and Cosmetic Act), please include the priority review voucher number assigned when the medical countermeasure product was approved. See FDA's Draft Guidance for Industry: Material Threat Medical Countermeasure Priority Review Vouchers for further information. FDA's guidance can be found on FDA's web site: https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM592548.pdf
9.	**EXCEPTIONS:** The application is for an orphan drug product. Under section 736(a) (1) (F) of the FD&C Act, a human drug application is not subject to an application fee if the proposed product is for a rare disease or condition designated under section 526 of the FD&C Act (orphan drug designation) AND the application does not include an indication that is not designated. A copy of the FDA letter granting orphan designation should be included with the BLA/NDA submission.
10.	**WAIVER:** Complete this section only if a waiver of user fees, including a small business waiver, has been granted for this application. A copy of the official FDA notification that a waiver has been granted must be provided with the BLA/NDA submission.

Form FDA 3397 (04/19) (BACK)

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You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
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